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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/581,380 | 06/01/2006 | Robertus Martinus M. Diks | F7743(V) | 3881 |

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| EXAMINER | |
|---|---|
| SMITH, PRESTON | |
| ART UNIT | PAPER NUMBER |
| 4152 | |

| MAIL DATE | DELIVERY MODE |
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| 10/30/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/581,380 | DIKS ET AL. | |
| | Examiner | Art Unit | |
| | PRESTON SMITH | 4152 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/27/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claim 10** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 10** provides for the use of an emulsifier with an HLB value at or below 16 to reduce age gelation in sterilized protein containing suspensions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claim 10** is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Podutoori Ravinder Reddy, US-Patent 6,045,853 in view of "Dairy Consultant, Milk Pasteurization basics".**

Referring to **claim 1**, Reddy teaches an oil or fat phase that contains combinations of emulsifiers (column 4, lines 47-50) that can be combined with an aqueous phase (column 3, lines 40-41. This aqueous phase could contain milk as mentioned in column 4, line 19. Milk is an aqueous suspension comprising protein. (Furthermore, it is shown in paragraphs 0057 and 0060 of applicant's specification that milk is an aqueous suspension). The combination of the emulsifiers from the fat phase with the milk from the aqueous phase would create an aqueous suspension comprising fat and dairy protein (column 4, line 23). Further, the emulsifier has an HLB of 3-4 (column 4, line 39. 3-4 is less than 16).

Reddy does not specifically teach using sterile milk however, as can be seen from the NPL document, "Dairy Consultant, Milk Pasteurization basics", Ultra high temperature (UHT) treatment is typically used to treat milk to eliminate harmful microbes

(page 3, Sterilization of Milk section). It is not known if the milk used in Reddy has undergone this sort of treatment however to one of ordinary skill in the art at the time the invention was made, it would have been obvious to use UHT to kill harmful microbes that may be present in milk. Since some microbes present in milk (such as Clostridium Botulinum) are known to cause damage to health, to one of ordinary skill in the art, it would be obvious to use UHT taught "Dairy Consultant, Milk Pasteurization basics" to treat the milk used in Reddy before further use to reduce the chances of harmful microbial infection.

Referring to **claim 2,** Reddy teaches protein (column 4, line 23) however it is not known if it is in the amount of 0.5-10%. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the protein percentages, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Referring to **claim 3**, Reddy teaches dairy protein (column 4, line 23).

Referring to **claim 4**, Reddy teaches monoglycerides (column 4, lines 35-40).

Referring to **claim 5**, Reddy teaches monoglycerides (column 4, lines 35-40).

Referring to **claim 6**, Reddy teaches monoglycerides (column 4, lines 35-40).

Referring to **claim 7**, Reddy teaches the monoglyceride emulsifier to be from 0.05-0.5% (column 4, lines 35-40). The claimed range of 0.05-0.2% falls within the range of Reddy. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Reddy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to **claim 8**, Reddy and the claim differ in that Reddy teaches fat between 5 and 30% (column 4, line 2-3) however Reddy does not teach the exact same proportions of 0.1-8% as recited in the instant claim.

To one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions

taught by Reddy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to **claim 9**, Reddy teaches soybean oil (column 3, line 47) which is known to contain high levels of Phytosterols (see NPL, List of Foods (with High Phytosterol) That Help Lower Serum Cholesterol). (Also, in paragraph 0048, applicant cites "Influence of Processing on Sterols of Edible Vegetable Oils", S. P. Kochhara. It can be seen on page 262, 3rd paragraph of this reference that soy bean oils contain phytosterols). Since soy bean oils are added in Reddy, phytosterols would be added.

Referring to **claim 10**, Reddy teaches a monoglyceride emulsifier (column 4, lines 35-40). As mentioned in examiners address of **claim 1**, this emulsifier which has an HLB of 3-4 (column 4, line 39. 3-4 is less than 16) can be combined with milk (see again column 3, lines 40-41 and column 4, line 19) (the sterilized protein containing

suspension is milk). The product of Reddy would have age reducing gelation properties since it contains all of the components of this claim.

## *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US-Patents: 6,045,853, 4,888,194, 4,305,970, 4,917,915, 3,917,859, 4,748,028, 5,077,077, 5,332,595, 5,609,904, 4,421,778, 4,853,243, 6,764,707.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRESTON SMITH whose telephone number is (571)270-7084. The examiner can normally be reached on 6:30am -5:00pm, Mon-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

prs

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4152